



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/813,209 | 03/29/2004 | Gunter A. Hofmann | GTI 1360-3 | 5135 |

7590 12/01/2004

Daniel M. Chambers
BioTechnology Law Group
658 Marsolan Avenue
Solana Beach, CA 92075-1931

EXAMINER

FASTOVSKY, LEONID M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3742

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/813,209 | Applicant(s) HOFMANN ET AL. | |
| | Examiner Leonid M Fastovsky | Art Unit 3742 | |
| | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maclaughlin et al (22002/0102729) in view of McKinnon Jr. et al (5,505,697) and further in view of Riddle et al (6,035,234).

Maclaughlin teaches substantially the claimed invention comprising injection by electroporation that involves the application of a pulsed electric field to create transition pores in the cellular membrane without causing damage to cell and thereby allows for introduction of exogenous molecules (page 1, [5]) and the preferred embodiments are by pulse voltage delivery to cells in combination with needle or needle free injection, or by direct applied pulse voltage wherein the electroporation device's electrodes are pressed directly against the targeted tissue or cells, such as for example epidermal cells (page8, [103]). Also, Maclaughlin teaches to deliver nucleic acid vaccines in a more efficient manner (page 9, [118]). McKinnon teaches needle free injectors 20, and Riddle teaches an electrotransport device for delivering therapeutic agents through electrodes 108 and 112. It would have been obvious to one having ordinary skill in the art to use needle free injectors in Maclaughlin's invention as taught by McKinnon and electrodes as taught by Riddle to introduce biologically active agents and to select and /or adjust the desired voltage

Art Unit: 3742

amplitude and/or the duration of pulsed voltage in order to properly treat a patient as taught by Maclaughlin (page 4, [42]).

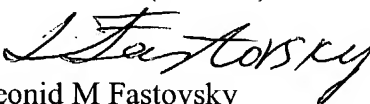
Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5667491 (method of introducing a biologically active agent).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonid M Fastovsky whose telephone number is 571-272-4778. The examiner can normally be reached on M-Th. 8.00 am -6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on 571-272-4777. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Leonid M Fastovsky
Examiner
Art Unit 3742

lmf